**In the Specification**

Please substitute the following amended paragraph for the paragraph beginning at page 2, line 34 (also identified as paragraph [0010] in the corresponding U.S. Pub. No. 2006/0167069), and previously amended in the Preliminary Amendment of March 2, 2005:

[0010] The present invention provides a pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, characterized in that the pharmaceutical composition has an enhanced bioavailability as compared to metaxalone tablets commercially available in the United States of America under the trade name Skelaxin® and approved by the United States Food and Drug Administration under the New Drug Application No. 13-217 (incorporated herein by reference) when they are administered to a patient under fasted conditions, i.e., on an empty stomach. The pharmacokinetics of Skelaxin® are provided in papers of record in the FDA in connection with New Drug Application No. 13-217, which states:

> "In a single center radominzed, two-period crossover study in 42 healthy volunteers (31 males, 11 females), a single 400 mg SKELAXIN (metaxalone) tablet was administered under both fasted and fed conditions. Under fasted conditions, mean peak plasma concentrations ($C_{max}$) of 865.3 ng/mL were achieved within 3.3 +/- 1.2 hours (S.D.) after dosing ($T_{max}$). Metaxalone concentrations declined with a mean terminal half-life ($t_{1/2}$) of 9.2 +/- 4.8 hours. The mean apparent oral clearance (CL/F) of metaxalone was 68 +/- 34 L/h. In the same study, following a standardized high fat meal, food statistically significantly increased the rate ($C_{max}$) and extent of absorption (AUC(0-t), AUCinf) of metaxalone from SKELAXIN tablets. Relative to the fasted treatment the observed increases were 177.5%5, 123.5%, and 115.4%, respectively. The mean Tmax was also increased to 4.3 +/- 2.3 hours, whereas the mean t1/2 was decreased to 2.4 +/- hours. This decrease in half-life over that seen in the fasted subjects is felt to be due to the more complete absorption of metaxalone in the presence of a meal resulting in better estimate of half-life. The mean apparent oral clearance (CL/F) of metaxalone was relatively unchanged relative to fasted



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administration (59 +/- L/hr). Although a higher $C_{max}$ and AUC were observed after the administration of SKELAXIN (metaxalone) with a standardized high fat meal, the clinical relevance of these effects is unknown." *(See* http://www.fda.gov/cder/foi/label/2002/13217s036lbl.pdf (posted 9/5/02)).

The term "enhanced bioavailability" as referred to herein means that in comparative bioavailability study wherein Skelaxin® tablet (New Drug Application No. 13-217) as reference product and the pharmaceutical composition of the present invention having an amount of metaxalone equivalent to that in the reference Skelaxin® tablet are given to human volunteers under fasted conditions (on an empty stomach), the extent of absorption as measured by the ratio of area under the plasma concentration versus time curve for the test versus the reference product is greater than 120% and the rate of absorption is faster as measured by the mean time (mean $T_{max}$) taken to reach the peak plasma concentration which is less than for the reference product. ~~The pharmaceutical composition of the present invention may also be a controlled or sustained release composition whereby the term "enhanced bioavailability" means that in a comparative bioavailability study wherein Skelaxin® tablet as the reference product is given in multiple doses and the controlled release pharmaceutical composition of the present invention having a total amount of metaxalone equivalent to the amount in the multiple doses of Skelaxin® is given to human volunteers under fasted conditions; the ratio of area under the plasma concentration versus time curve for the test versus the reference product is greater than 120%.~~



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